EXHIBIT 40

EXPERT REPORT

Analysis of Distributor and Manufacturer Regulatory Compliance to Maintain Effective Controls for the Prevention of Diversion of Controlled Substances

Prepared by
James E. Rafalski
37637 Five Mile Road #278
Livonia, MI 48154

- Administrative investigation resulted in an Administrative Memorandum of Agreement that remained in effect for three years.

As a DEA Diversion Investigator with 13 years of experience (2004-2017), I am uniquely qualified to offer expert opinions regarding compliance with federal regulations governing the distribution of controlled substances including oxycodone and hydrocodone. I am familiar with the DEA Diversion Investigators Manual and received training from the United States Department of Justice on suspicious order monitoring, data analysis from ARCOS, reporting of suspicious orders and the due diligence required before shipping an order flagged as suspicious. I directly participated in the successful prosecution of Masters Pharmaceutical which resulted in a case opinion from the highest federal court in the country (to date). I led the first action that led to a memorandum of agreement with a manufacturer for failure to maintain effective controls to prevent diversion and failing to design and operate an adequate suspicious order monitoring system.

Based (a) on my education, training and experience, (b) the law, regulation and practices in the area of CSA enforcement, and (c) on my review of document and testimony provided in this case (MDL 2804), I am of the opinion to a reasonable degree of professional certainty that there was a systematic, prolonged failure over many years by the defendant manufacturers and distributors to maintain effective controls against diversion of legitimate opioid prescriptions into the illicit market.[1] I am further of the opinion that this systematic failure was a substantial cause of the opioid epidemic plaguing the country and specifically in Cuyahoga County and Summit County. I am prepared to testify regarding the regulatory duties imposed by the CSA and federal regulations. I have been asked to review the documents produced by the defendants and depositions taken in MDL2804 and offer opinions regarding statutory and regulatory compliance.

I offer my opinions herein to a reasonable degree of professional certainty. I believe the facts stated herein are true and accurate and based on the record provided to me. I understand that the defendants continue to supplement discovery and have disclosed tens of millions of documents. I have relied upon the defendant's answers to Combined Discovery Requests (served on July 1, 2018) as a basic outline for evidence of compliance to reach my opinions.

I am being compensated at the rate of $300.00 per hour for the time I have spent related to this report. The hourly rate for my time spent testifying is $500.00 per hour. I have not previously provided expert testimony at trial or deposition. I have not authored any publications or articles. In addition to the documents and testimony cited within my report, I have also reviewed documents identified in the attached Schedule I.

[1] I provide all opinions in this report with a reasonable degree of professional certainty.

mean prior to a shipment." This statement along with the letter from DEA is an important communication that identifies the DEA was requiring the suspicious order system to identify single orders of controlled substances that must report immediately prior to being shipped.

2008 Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Report Suspicious Orders and Preventing Diversion of Controlled Substances.

In 2008 the HDMA posted on their website industry compliance guidelines that were titled, "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances." In the introduction section of the document appeared this comment:

> At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support security of controlled substances they deliver to their customers. Due Diligence can provide a greater level of assurance that those who purchase CS from distributors intend to dispense them flor legally acceptable purposes. Such due diligence can reduce the possibility that controlled substances within the supply chain will reach locations they are not intended to reach.[91]

On October 17, 2008, DEA Chief Counsel Attorney Wendy H. Goggins sent a written statement to HDMA President and CEO John M. Gray commending the HDMA for their efforts to assist their members in fulfilling the obligations regarding the Controlled Substance Act and corresponding regulations.[92]

The HDMA compliance guidelines document contains a general framework for a basic suspicious order monitoring system.[93] The document contains the following elements with accompanying suggested guidelines:

1. Know Your Customer Due Diligence
2. Monitoring for Suspicious Orders
3. Suspend/Stop an Order of Interest Shipment
4. Investigation of Orders of Interest
5. File Suspicious Order of Interest
6. Employees, Training and Standard Operating Procedures (SOPs)
7. Additional Recommendations
8. Glossary of Abbreviations

[91] February 10, 2012 Declaration of Joseph Rannazzisi, CAH_MDL_PRIORPROD_DEA12_00014479, 00014512.

[92] CAH_MDL_PRIORPROD_DEA12_00000825.

[93] CAH_MDL_PRIORPROD_DEA12_00000826.

d. Include a process and/or guidance/criteria for making the final determination that an order is, or is not, "suspicious";

e. Define a process for reporting to DEA under 21 C.F.R. Section 1301.74(b); and

f. Define a process for allowing release of a shipment, or cancellation of an order, as appropriate.[106]

19. If a distributor concludes an order is suspicious after conducting an investigation it is recommended the distributor make a determination whether they will subject future orders from the same customer for the same drug product to more rigorous scrutiny and/or consider whether to cease filling all future orders of that drug product or all controlled substances.[107]

L. DEA CHEMICAL HANDLERS MANUAL

Cardinal Health (and others) have responded to discovery referencing the DEA's Chemical Handlers Manual and/or the 1998 Reno Report as "guidance" provided by the DEA regarding its suspicious order monitoring system for Schedule II and III controlled substances, including prescription opiates.[108] It is worth noting that these guidelines relate to "Listed Chemicals", rather than Schedule II and III controlled substances, primarily focused on the sale of chemicals used to make illicit methamphetamine. "Suspicious orders" of Listed Chemicals are defined by 21 USC § 830(b)(1)(A) as orders of "extraordinary" size [based on a formula which generally multiples a monthly base weight average per base code by a multiplier (3x)]. Notably, the Chemical Handlers Manual also mandates:

> **When a regulated person suspects that an order may be intended for illicit purposes, good practice requires that every reasonable effort be made to resolve those suspicions. In addition to making required reports, the transactions should not be completed until the customer is able to eliminate suspicions.**[109]

Relying upon a threshold of "extraordinary" size fails to detect orders of "unusual size" and is not compliant with 21 CFR 1301.74(b). Nor is shipping suspicious orders after reporting. Further, reliance on this threshold also does not detect orders of unusual pattern or frequency.

M. MAINTENANCE OF EFFECTIVE CONTROLS AGAINST DIVERSION OF CONTROLLED SUBSTANCES

Registrants engaged in actively distributing controlled substances should implement measures to comply with the legal and regulatory requirements. These measures should be documented as a standard operating policy for the company and be distributed to all relevant

[106] *Id*. at CAH_MDL_PRIORPROD_DEA12_00000826, 00000837.

[107] *Id*.

[108] *See*, *e.g.*, CAH_MDL_PRIORPROD_HOUSE_0002207; CAH_MDL_PRIORPROD_DEA07_01198690.

[109] CAH_MDL_PRIORPROD_DEA07_01198690, 01198713.

employees. These standardized policies should be designed by distributors and manufacturers to take the utmost precautions to prevent diversion by maintaining the "closed system" of distribution. Included below are some key components that one would expect to see an operational system designed to maintain effective controls against diversion.

- Registrants must have a comprehensive system in place and conduct an investigation on a customer who will be purchasing controlled substances. The following are some of the activities utilized to establish a new customer:
    - The review to establish a new customer and begin distribution of controlled substances is a critical 1st step to ensures a potential customer has a business plan consistent with compliance to the Controlled Substances Act. The review should confirm the information provided by the potential customer is accurate. One commonly used procedure by distributors is to utilize a customer questionnaire which asks a series of questions similar to the following:
        - Past history of DEA registration to determine compliance history
        - Check of state and local licensure compliance.
        - Compliance history with state medical/pharmacy board
        - Review the business plan to determine legitimacy of the customer
        - Identify any affiliation with pain management doctors
        - Review percentage of controlled substance business
        - Identify any other distributors providing control substances
        - Review the percentage of cash payments and insurance payments
        - Review of pharmacy utilization reports
        - On-site inspection of customer
        - Internet search to determine any negative information

- 21 C.F.R. §1301.74(b) requires all manufacturers and distributors to design and operate a system to disclose to the registrant suspicious orders of controlled substances. This regulation states that suspicious orders include orders of an unusual size, orders deviating substantially for a normal pattern, and orders or an unusual frequency. The regulation further states a registrant shall inform the local DEA Division Office of suspicious orders when discovered by the registrant. The regulation indicates it is the responsibility of the registrant to **design** and **operate** a suspicious order monitoring system. The design of a suspicious order system must clearly identify when the order is identified by the system. A system that establishes thresholds which are legitimate needs of a customer identified through a comprehensive "know your customer" should consider any orders exceeding that threshold as a suspicious order. The identified order should not be shipped and reported to the DEA. The subsequent shipping of that order would be after a due diligence investigation has determined the order is being shipped for legitimate use. A suspicious order system to be effective contains many components which should include, but not limited to, the following:
    - Customer Types – Customers should be placed in into customer types based on the business activity identified through the due diligence documentation.

- Scope of Practice – The system should monitor and/or restrict customers to only allow the ordering of controlled substances by schedule and type which have been identified as required for the legitimate medical needs of the practice.
- Customer Tiers/Groups – Customers who have been placed into customer types should be segregated by size in a minimum of three groups, based on the volume of their ordering history identified through the due diligence documentation.
- Drug Types – A suspicious order system to be effective should design drug types with more specificity that by drug group or drug code. Monitoring controlled substances only by the drug code or drug family is too broad and reduces the effectiveness of the system. Thresholds should also be designed for those controlled substances identified with a higher probability of being targeted for diversion.
- Thresholds – A distributor must identify the amount of controlled substances required by a customer for the legitimate operation of their business based on the registrant's knowledge of the customers business model, due diligence investigation, comparison of purchase amounts by other similar customers. Thresholds should be calculated based on the history of usage of customer for a period of at least 12 months.
- Population – The geographic distribution of controlled substances should be analyzed with relevant population information of available end users. The cumulative amount of controlled substances being distributed by a registrant to a geographic area or region should be monitored to insure it is consistent with legitimate population consumption. Customers who identify an activity of filling prescriptions from patients traveling from outside the area require a thorough due diligence type investigation including the review of dispensing records (without patient information) to confirm the legitimacy of the activity.
- Pattern of Orders – Reviewing orders to determine if there are patterns of ordering of controlled and non-controlled drugs with a comparison with relevant industry information on the most frequently prescribed drugs. If the ordering pattern deviates from established levels or what would be normal for another similarly situated customer this could indicate potential diversion.
- Pattern of Orders - Are controlled substances ordered in combinations of frequently abused drugs. As an example, purchasing the combination of oxycodone or hydrocodone products with Soma, Valium, and/or Xanax. The pattern of ordering of known highly abused controlled substances in comparison of other drugs can indicate diversion.
- Frequency of Orders – The frequency of orders for controlled substances increasing disproportionately for specific controlled substances that have been identified as being highly diverted.
- Geographic Distribution – The density of like businesses in geographic areas should be reviewed. Further, there should be a comparison of like customers in similarly situated geographic areas for deviation of volume and/or pattern of controlled substance orders. The system should identify large volume of controlled substances

consistently being received from a customer(s) in a state, county and city/township that does not have the appropriate customer base density.

- A robust and well-documented due diligence program is key for every compliance system to identify suspicious orders of controlled substances. As orders of controlled substances are identified due to factors such as size, pattern, or frequency, those orders may only be shipped if any suspicion is dispelled after adequate due diligence is conducted and it is determined that such orders are not likely to be diverted for illicit purposes. The elements and procedures involved in a due diligence compliance program for suspicious orders should be contained in a standard operation policy and should be readily available to all employees whose responsibilities touch on suspicious order monitoring. Characteristics of a robust due diligence should include the following:

    - An established procedure and criteria for setting threshold quantities.
    - The person or department who is responsible for approving threshold quantities is specifically identified.
    - A procedure for adjusting threshold quantities that requires thorough review and documentation.
    - Justification for the increase or decrease of thresholds documented by the registrant, and made after a review of factors such as the following:
        - Analysis of historical orders from the customer as well as any previous adjustments in thresholds and the justification previously provided
        - Analysis of the patient population serviced by the customer
        - Analysis of the physician population serviced by the customer
        - Analysis of the results of an adequate on-site customer review program
        - Analysis of other factors that could indicate to the registrant whether or not controlled substances are likely to be diverted for illicit purposes
    - Compliance review programs that have independent authority from other corporate entities/divisions to review thresholds as well as to approve or disapprove customers or threshold adjustments.
    - Sales role (if any) in the compliance review program must be appropriately managed.
    - On-site review includes the acquisition and review of utilization report.
    - Request for threshold changes necessitates an on-site review.
    - The person(s) is specifically identified who is responsible for reporting suspicious orders to the DEA.
    - Orders reported as suspicious that are subsequently shipped by the registrant have sufficient due diligence review being conducted and documented prior to distribution.

- The documentation of due diligence performed and the results thereof being retained
- Suspicious orders also being reported to states where applicable.
- Suspicious orders being reported as drug families and by individual drugs.
- Sufficient training and education for all involved in the distribution of controlled substances.

Almost as essential as the due diligence being conducted is that efforts made to dispel suspicions and the results thereof are adequately documented and retained. Thorough recordkeeping and documentation of the steps taken to justify flagged orders are necessary not only to explain why decisions were made in any particular instance, but also to inform future decisions regarding flagged orders. One important aspect of every due diligence review should always be an examination of the historical transactions of the customer who placed the flagged order. Such an examination is necessary to evaluate trends over time and to inform decisions about whether or not orders of controlled substances are likely to be diverted into illicit channels. For purposes of conducting a historical review of a customer when evaluating a flagged order, if prior due diligence investigations are not adequately documented and retained, they may as well have not occurred at all.

As explained above, the goal of suspicious order monitoring is to ensure that bulk orders of controlled substances are being shipped for legitimate purposes rather than being diverted for illicit purposes. A suspicious order monitoring system has a self-policing aspect with the twin aims of both stopping the shipment of orders at risk of diversion and investigating those who have placed orders that are identified as suspicious. Not shipping a suspicious order is only part of the equation. The other parts are investigating the buyer and the circumstances surrounding the order and, if necessary, reporting the suspicious order to the DEA. Any order that is suspicious requires action to dispel suspicion and confirm legitimacy. Otherwise the order should not ship. When a distributor neglects to dispel suspicion and ships anyway, the risk of diversion does not disappear when the order ships. For this reason, any future order or shipment to that particular pharmacy or buyer should not ship until an investigation of the initial suspicious order occurs because there is an outstanding concern about the past shipment that has not been addressed. Otherwise, a distributor is potentially sending larger and larger quantities of controlled substances to a buyer that is under suspicion of being a diversion risk. The suspicious order monitoring system failures described above directly led to massive quantities of pills being shipped to buyers who had placed suspicious orders of controlled substances. These orders never should have shipped until after the suspicion of diversion was dispelled.

III. Identifying Suspicious Orders Distributed in CT1

I have described in this report the ways in which distributor and manufacturer defendants' inadequate response to their statutory and regulatory requirements to maintain effective controls related to the sales of prescription opioids would potentially cause the diversion of these pills for non-medical use. I have reviewed five suspicious order methodologies, some of which were

to determine whether there was a theft of product.[443] [444] **Period #2 Early to Mid-2009 until March 2014**

1. Item Review Reports[445]

In 2007 CVS hired Buzzeo to help create DEA control drug standard operating procedures. This engagement lead to the manuals identified above as the "CVS Distribution Center Controlled Drug - DEA Standard Operating Procedures (SOPs) Manual." As part of the engagement, in late 2008-early 2009, Buzzeo delivered to CVS an "SOM model … designed to 'pend' an order which may be classified as a 'suspicious' order for DEA reporting purposes."[446] The SOM model consisted of complex multiple logistic regression algorithms and was designed to pend any order with a score of .15 or higher. The IRR was a print-out that consisted of all controlled drug orders for that day that were identified as potentially suspicious by the SOM algorithm. This was a daily report that was run five days per week. As is described in the Due Diligence Conducted section below, CVS only performed due diligence on a small percentage of the orders identified in the IRR as potentially suspicious.

The IRRs had some specific problems that fit within the time periods below but it also had one overarching issue that continued from mid-2009 until March, 2014 – when performing the calculation of whether the order was suspicious, the IRRs did not consider orders delivered to CVS pharmacies by outside vendors.[447] CVS had full access to every order its pharmacies placed to outside vendors but did not incorporate this information in its SOM system. Maintenance of effective controls requires CVS to utilize all relevant transaction information. Not surprisingly, the VIPER reports which are used as inventory tools and to gauge whether there is a loss of product from theft automatically incorporates outside vendor information. [448]
The outside vendor issue was not rectified until the new AGI SOM program was implemented in 2014. As late as January of 2013, CVS was analyzing the potential risks of not tracking orders that its pharmacies placed to outside vendors and concluded that it needed to due to the "DEA 'Know Your Customer' requirements."[449] CVS recognized that in order for the "dispensing data in the algorithm to be useful, we must account for all controlled substances ordered."[450] In fact, a

[443] Burtner Depo., 384:12–21.

[444] Dugger Depo., 104:12–22.

[445] During this period the IRR was the primary SOM process used by CVS. However, CVS also continued to use the Pickers and Packers and PDMR Viper reports in conjunction with the IRR.

[446] *See* Cegedim Dendrite Compliance Solutions Powered by BuzzeoPDMA "Descriptive Over Document: Cegedim Dendrice Suspicious Order Monitoring (SOM) Model" Version 1.0 – December 2008. CVSMDLT1-000123386–000123392).

[447] Burtner Depo., 284:21 – 285-20.

[448] Burtner Depo., 382:20 -387:17.

[449] CVS-MDLT1-000103328, at 28.

[450] CVS-MDLT1-000103328.

Participant notes from this meeting indicate that Mr. Mapes advised the audience not to "confuse suspicious order report with an excessive purchase report. They are two different things."[560]

3. **Bancroft Algorithm (2008 to 2012):**

Phase I (August 2009 – September 2010)

As early as 2005 and 2006, Walgreens acknowledged that its SOM policies were inadequate and did not meet industry and legal standards, however, Walgreens did not institute a SOM program at that time.[561] In March 2008, in response to three of Cardinal Health's DCs being shut down by the DEA for suspicious drug ordering violations, Walgreens formed a five department "team" to finally "begin creating" a SOM program,[562] and, in June 2008, developed a new SOMS algorithm to begin to address the inadequacies of Walgreens's SOM policies.[563] Despite years of knowledge that its SOM was insufficient, and despite developing a sophisticated algorithm in 2008, Walgreens did not practically implement its SOM program until 2009, when it began to pilot the algorithm with respect to orders from seven (7) Walgreens stores.[564] The algorithm Walgreens developed in 2008 and began to test in August 2009 flagged the regular periodic orders for controlled substances orders that these seven Walgreens stores placed to Walgreens Distribution Centers for "tolerance" (size of the order) and "frequency" (how often the period orders were placed).

During the substantial majority of Phase I, the SOMS program was only implemented as a "pilot" or "proof of concept". [565] While the Phase I SOMS flagged some orders from these seven stores as suspicious, during Phase I Walgreens did not halt orders that violated the algorithm or take any other comprehensive steps to prevent the flagged orders from being shipped or filled.

The SOMS order flagging pilot was not implemented chainwide until September 2010.[566]

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[560] Acquired_Actavis_00441354 at 441355.

[561] WAGMDL00757193 ("internal controls that ensure compliance with DEA regulations … pertain[ing] to all company DCs … should be addressed to void potential DEA sanctions", noting that these issues had been pending and "un-remediated" since audits in 2005 and 2006, and included "suspicious controlled drug order processing and reporting" and "lack of formalized CII controlled substance policies and procedures."); *See also* WAGMDL00709508 (""suspicious ordering report is inadequate"); WAGMDL00709510 ("formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient").

[562] WAGMDL00659801 at 818; WAGMDL00709395.

[563] WAGMDL00624527.

[564] WAGMDL00667936, at 938 and 940; *see also* WAGMDL00658227.

[565] *See* E. Bratton Deposition at 207:1 to 210:7; WAGMDL00325170

[566] *See* E. Bratton Deposition at 208:10 to 209:24.